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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,256	07/15/2003	Orla M. Conneely	HO-P02682US1	9752

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,256	CONNEELY ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24 and 65-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 65-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed October 18, 2005 on February 13, 2006, is acknowledged.

Claim Disposition

2. Claims 1-23 and 25-64 have been canceled. Claims 24 and 65-77 are pending and are under examination.

Withdrawn-Specification Objections

3. Previous objection to the specification and the abstract are withdrawn by virtue of submission of an amendment.

Drawing

4. The drawings filed on February 13, 2006 are accepted by the examiner.

New-Specification Objection

5. The specification is objected to because of the following informalities:

The specification is objected to because the "Brief Description of the Drawings" has incomplete descriptions for the following figures: Figure 7 depicts 7A-7C, however,

this is not described on page 6 of the specification; Figure 8 depicts 8A-8B; Figure 9 depicts 9A-9B; Figure 12 depicts 12A-12B; on page 7, Figure 14 depicts 14A-14C; Figure 18 depicts 18A-18N; Figure 19 depicts 19A-19M and Figure 20 depicts 20A-20N. Correction is required.

Claim Objection

6. Claim 71-77 are objected to because of the following informalities:

Claim 71-77 are objected to because the scientific name of the organisms recited in the claims have not been italicized, for example "*Aspergillus*".

Correction is required.

Maintained and Amended-Claim Rejections - 35 USC ∋ 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 24 and 65-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a process for producing human lactoferrin which comprises culturing a transformant eukaryotic cell containing a recombinant plasmid, said plasmid comprising a plasmic vector having a polydeoxyribonucleotide which codes for a human lactoferrin protein in a suitable nutrient medium until the human lactoferrin protein is formed and isolating the human lactoferrin protein, however, the claimed nucleic acid is only defined by function (i.e., encoding a protein) not by a structure. Thus, there is no indication of which nucleic acid encodes the protein. Thus the claims lack adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention. In addition, the claims are directed to a "mammalian cell that is immortalized" or "insect cells", for example, however, the instant specification does not provide adequate description regarding transformation of said cells with a human lactoferrin. No empirical evidence is provided of being able to successfully transform all the cells recited in claims 65-70 to demonstrate possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997).* Therefore, a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying

characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. *See MPEP 2163.*

Further, *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991)*, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of encoded proteins, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993). See MPEP 2163.*

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

8. Claims 24 and 65-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the structures set forth in SEQ ID NOS: 1-2, yeast and fungal cells exemplified in the specification and within the art, does not reasonably provide enablement for any DNA encoding a human lactoferrin protein transformed into any mammalian cell or mammalian immortalized cell or any insect cell, for example. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988)*. The factors most relevant to the instant invention are discussed below.

The claimed invention does not provide a correlation between structure and function for the encoding nucleic acid and the encoded human lactoferrin protein. Therefore, the instant specification is not commensurate in scope with the claims which reads on any nucleic acid. In addition, the claims are directed to a "mammalian cell that is immortalized" or "insect cells", for example, however, the instant specification does

not provide support regarding transformation of said cells with a human lactoferrin. No empirical evidence is provided of being able to successfully transform all the cells encompassed in claims 65-70 to be considered enabling. The art recognizes *Aspergillus awamori* expressing recombinant human lactoferrin (Sun et al., Biological Crystallography, vol. 55, February 1999, Abstract), the expression of human proteins in *Pichia pastoris* (Cereghino et al., FEMS Microbiology Reviews, vol. 24, 2000, pages 45-66), recombinant human lactoferrin expressed in BHK cells (FEBS Letters, vol. 365, 1995, pages 57-60) and glycoprotein in insect cells (Marchal et al., Biol. Chem., vol. 382, pages 151-159, Feb. 2002), however, the breath of the claims encompass any or all mammalian cell or immortalized mammalian cells or insect cells, for example. It is noted that claim 70 recites "wherein the insect cell is SF9 (*Spodoptera frugiperda*), however, no exemplification is provided of said cells successfully transformed with human lactoferrin utilizing the vector recited in claim 24. Absent guidance/direction in the instant specification with regard to the structural properties of the products claimed and the cells that can be successfully transformed with the human lactoferrin protein, undue experimentation would be required to practice the claimed invention commensurate in scope with the claims. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification. Therefore, applicants have not provided sufficient guidance to enable one of skill in the

art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 67 and 71 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 67 and 71 are confusing because claim 67 recites "fungal cell" and claim 71 recites "fungal cell is selected from the group consisting of *Aspergillus*, *Saccharomyces, Kluyveromyces* and *Pichia*" and the Markush listing includes fungal cells and yeast cells. It is suggested that claim 71 is amended to read the fungal cell is *Aspergillus* and a new claim is added to depend from claim 68 to read "yeast cell selected from the group consisting of *Saccharomyces*, *Kluyveromyces* and *Pichia*". The art recognizes that yeast cells are fungi that grow as single cells, however, the fact that claim 67 recites "fungal cell" and claim 68 recites "yeast cell", claim 71 should also provide a distinction between yeast and fungal cell (as the art recognizes that yeast and fungi reproduce differently and have different shapes, thus are distinguishable).

Maintained-Basis For NonStatutory Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 24 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent Application number 6,635,447. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *See*

In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim is directed to a process for producing human lactoferrin which comprises culturing a transformant eukaryotic cell containing a recombinant plasmid, said plasmid comprising a plasmic vector having a polydeoxyribonucleotide which codes for a human lactoferrin protein in a suitable nutrient medium until the human lactoferrin protein is formed and isolating the human lactoferrin protein. The claims in the instant application are also directed to eukaryotic cells that are mammalian. The patented claims are directed to a process for producing lactoferrin which comprises culturing a transformant eukaryotic cell containing a recombinant plasmid, said plasmid comprising a plasmic vector having a polydeoxyribonucleotide which codes for a lactoferrin protein in a suitable nutrient medium until the lactoferrin protein is formed and isolating the lactoferrin protein. The two sets of claims differ as the patented claim 1 does not recite "human lactoferrin", however, dependent claim 2 of the patent recites that the cDNA used codes for human, bovine or porcine lactoferrin. Therefore, the two sets of claims are obvious variations of each other as the patented claims are a genus over the instant claims.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the same material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for

example the species human in the instant claim 24 that is contained in the genus as disclosed in claims 1-2 of the patent because it clarifies the claim by providing the specific species. Thus, the instant claims are an obvious variation of the patented claims, therefore prima facie obvious.

This is an obvious-type double patenting rejection.

Withdrawn- Basis For NonStatutory Double Patenting

12. Previous rejection under 35 U.S.C. 103, Obvious-type Double Patenting over U.S. Patent Nos. 6,100,054 and 5,571,691 are withdrawn by virtue of submission of a Terminal Disclaimer.

Response to Arguments:

13. Applicant's response filed on February 13, 2006 has been considered. Note that the rejections under 35 U.S.C. 103, Obvious-type Double Patenting remains in part and the rejection under 35 U.S.C. 112, first paragraph remains. Note that new grounds of rejection has been instituted under 35 U.S.C. 112 first paragraph enablement and 112, second paragraph for the reasons stated above. In addition, new objections to the claims and specification has been instituted for the reasons stated above.

With regard to the Obvious-type Double Patenting rejection, the response on page 14 state that a Terminal Disclaimer has been filed. It is noted that applicant filed a Terminal Disclaimer and the appropriate fees over U.S. Patent Nos. 6,100,054 and 5,571,691

and stated that priority is now claimed to U.S. Patent No. 6,635,447 as a parent to this divisional application. The record reflects that the instant application is a divisional of U.S. Patent No. 6,635,447 and it is noted that a restriction requirement was made in the parent application based on distinct structural properties, however, the instant claims do not recite a structure. Therefore, the two sets of inventions are obvious variations of each other and applicant did not file a Terminal Disclaimer over U.S. Patent No. 6,635,447. Thus, the rejection remains.

The rejection under 35 U.S.C. 112, first paragraph written description remains, however, has been amended. Applicant on page 14 of the response states that "the examiner's attention is directed to Fig 1, 2 and 18 and SEQ ID NO:1 and 2" with regard to the structure of the nucleic acid sequence for human lactoferrin. Applicant is reminded that the limitations of the specification cannot be read into the claims. In addition, MPEP 2163 states that an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997).* Therefore, a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic

acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. Thus, it is clear that a correlation between structure and function is necessary. Further, MPEP 2163 also state that (citing Amgen, 927F.2d at 1206, 18 USPQ 2d at 1021), "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials". Thus, for the reasons stated above and herein the rejection remains.

Conclusion

14. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner 4/26/06

HOPE ROBINSON
PATENT EXAMINER